



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/693,428 | 10/24/2003 | Claudia A. Robbins | 10031294-1 | 2017 |

7590 05/09/2007
AGILENT TECHNOLOGIES, INC.
Legal Department, DL 429
Intellectual Property Administration
P. O. Box 7599
Loveland, CO 80537-0599

| |
|----------|
| EXAMINER |
|----------|

CROW, ROBERT THOMAS

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1634

| | |
|-----------|---------------|
| MAIL DATE | DELIVERY MODE |
|-----------|---------------|

05/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/693,428

Applicant(s)

ROBBINS ET AL.

Examiner

Robert T. Crow

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 February 2007 has been entered.

Status of the Claims

2. This action is in response to papers filed 26 February 2007 in which claims 1, 19, and 23-24 were amended, no claims were canceled, and no new claims were added. All of the amendments have been thoroughly reviewed and entered.

The interview summary is acknowledged and the interview record is complete.

The previous rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

Claims 1 and 3-24 are under prosecution.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 and 3-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1 and 3-24 are indefinite in claims 1 and 19 each of which recites the limitation "up to about 10 mm" in line 9 of claim 1 and in line 11 of claim 19. The phrase "up to" typically indicates a

Art Unit: 1634

maximum point; however, the phrase "up to" is controverted by the term "about," which implies that values above and below the indicated amount are permitted. Therefore, the juxtaposition of these two terms makes it unclear what particle retention is encompassed by the claim.

B. Claim 22 is indefinite in the recitation "a specific weight ranging from about 75 g/m² to about 300 g/m²" at the end of the claim. "Specific weight" is an art recognized term for density, which has units of mass/cubic area rather than mass per square area. It is thus unclear what the limit of the specific weight of the filter material is because the specific weight of the filter material is defined using a unit of measurement that is incomplete and therefore unable to describe the desired characteristic of the material.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1634

7. Claims 1, 3-10, 12-16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Qiagen (The Qiagenologist Application Protocols, 3rd edition, Qiagen Inc., Chatsworth, CA, pages 1-53 (1990)) in view of Lineau et al (U.S. Patent Application Publication No. US 2002/0072110 A1, issued 13 June 2002).

Regarding claim 1, Qiagen teaches a method of preparing a sample substantially free of genomic DNA. In a single exemplary embodiment, Qiagen teaches forming a lysate from liver cells (page 31, steps 1-2). The lysate contains genomic DNA and RNA. Qiagen further teaches contacting a pre-filtration column with said lysate; namely, the lysate is contacted with a Qiagen-tip (page 31, step 9), which is a column (page 3). Genomic DNA binds to said filter material (page 4, last paragraph and Table 1 on page 5). Total RNA is then eluted from the Qiagen-tip using buffer QRU to form a sample preparation; namely, (page 31, step 12). Buffer QRU does not have enough NaCl to elute the genomic DNA from the column (Page 33 and Table 1 on page 5); thus, the sample preparation is substantially free of genomic DNA. An RNA precipitate is then formed by adding the organic solvent isopropanol (page 31, step 13).

Qiagen does not teach contacting the precipitate with a polymeric membrane.

However, Lineau et al teach a method of preparing a nucleic acid sample (paragraph 0031). In a single exemplary embodiment, Lineau et al teach forming a lysate from a biological sample (paragraph 0007), followed by forming a precipitate of the nucleic acid by adding the alcohol isopropanol, which is an organic solvent (paragraphs 0036 and 0055). The precipitated nucleic acid is then trapped on a polymeric membrane (paragraph 0039), followed by collecting the nucleic acid containing precipitate (paragraph 0039). Lineau et al further teach the membrane contacting step has the added advantage allowing incorporation into high throughput applications and without substantially affecting the yield of the isolated nucleic acid (paragraphs 0037 and 101), wherein the nucleic acid that is purified is RNA (paragraph 0031).

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe includes

Art Unit: 1634

functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph). Lineau et al teach the polymeric membrane is a nylon membrane having a pore size, and thus a particle retention, of 5 microns (paragraph 0023), which is up to 10 microns. Claim 3 limits the membrane to nylon membranes. Thus, the nylon membrane of Lineau et al acts as a passive physical barrier as required by the claims.

It would therefore have been obvious to a person of ordinary skill at the time the claimed invention was made to have modified the method of Qiagen with the additional steps of RNA purification as taught by Lineau et al with a reasonable expectation of success. The modification would result in an RNA containing precipitate as taught by Qiagen, which is then subjected to the method of Lineau et al that follows the addition of the organic solvent to form a precipitate as also taught by Lineau et al. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in a method of preparing an RNA sample having the added advantage of incorporation into high throughput applications as explicitly taught by Lineau et al (paragraphs 0037 and 101).

Regarding claims 3-4, the method of claim 1 is discussed above. Lineau et al also teach the polymeric membrane is a nylon membrane (i.e., claim 3) having a pore size, and thus a particle retention, of 5 microns (paragraph 0023), which is from about 0.1 to about 10 microns (i.e., claim 4).

Regarding claim 5, the method of claim 1 is discussed above. Qiagen teaches the removal of essentially all of the genomic DNA uses a prefiltration technique; namely, the lysate is contacted with a Qiagen-tip (page 31, step 9), which is a column comprising a filter material (page 3).

Regarding claims 6-8, the method of claim 1 is discussed above. Qiagen also teaches the lysate is formed with a chaotropic agent; namely, lysis is performed with buffers R1-R4, which comprises 4 M guanidine isothiocyanate (i.e., claims 6-8; pages 31 and 33).

Art Unit: 1634

Regarding claims 9-10, the method of claim 1 is discussed above. Qiagen also teaches the sample is an animal tissue; namely, liver tissue (page 31), which is an organ extract.

Regarding claim 12, the method of claim 1 is discussed above. Qiagen also teaches the precipitate is essentially free of DNA; namely, buffer QRU does not have enough NaCl to elute the genomic DNA from the column (Page 33 and Table 1 on page 5), and the sample preparation is therefore substantially free of genomic DNA.

Regarding claim 13, the method of claim 1 is discussed above. Qiagen also teaches the lysis buffer (i.e., buffers R1-R4) comprises β -mercaptoethanol (page 33).

Regarding claim 14, the method of claim 1 is discussed above. Qiagen also teaches the organic solvent is isopropanol (page 31, step 13).

Regarding claim 15, the method of claim 1 is discussed above. Qiagen also teaches the precipitate is washed; namely, step 14 is a wash step (page 31), which occurs after the steps of membrane steps of Lineau et al. It is noted that the instantly claimed wash step is not required to take place before the final collection step of independent claim 1; rather, the instantly claimed wash step is only required to be performed after the polymeric membrane contacting step. In addition, the courts have held that selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results (*In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946). See MPEP 2144.04 IV.C.

Regarding claim 16, the method of claim 15 is discussed above. Lineau et al further teach the nucleic acids trapped on the membrane are washed with wash buffer comprising a buffering agent and an alcohol (paragraph 0059). The washing step has the added advantage of gently separating the trapped nucleic acid from associated proteins, lipids, and cell debris without substantially effecting the yield of the isolated nucleic acid (paragraph 0059), wherein the nucleic acid is RNA (paragraph 0031).

It would therefore have been obvious to a person of ordinary skill at the time the claimed invention was made to have further modified the method of Qiagen in view of Lineau et al with the additional wash step as taught by Lineau et al with a reasonable expectation of success. The ordinary

Art Unit: 1634

artisan would have been motivated to make such a modification because said modification would have resulted in a method of preparing an RNA sample having the added advantage of allowing gentle separation of the trapped RNA from associated proteins, lipids, and cell debris without substantially effecting the yield of the isolated RNA as explicitly taught by Lineau et al (paragraphs 0037 and 101).

Regarding claim 18, the method of claim 16 discussed above. Lineau et al also teach the wash buffer comprises 70% alcohol and Tris H-Cl (paragraph 0101). The alcohol is ethanol (paragraph 0055), and Tris H-Cl buffers maintain a pH from about 6 to about 9 (paragraph 0111).

8. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Qiagen (The Qiagenologist Application Protocols, 3rd edition, Qiagen Inc., Chatsworth, CA, pages 1-53 (1990)) in view of Lineau et al (U.S. Patent Application Publication No. US 2002/0072110 A1, issued 13 June 2002) as applied to claim 16 above, and further in view of Whitlow et al (U.S. Patent No. 5,869, 620, issued 9 February 1999).

Regarding claim 17, the method of claim 16 discussed above on pages 3-6. Qiagen teaches a wash solution comprising 15% ethanol and the buffering agent MOPS at pH 7 (i.e., buffer QA; step 11, pages 31 and 33), as well as buffers comprising guanidine (i.e., buffers R1 and QA; step 11, pages 31 and 33). Lineau et al also teach a wash solution comprising a buffering agent to maintain a pH from about 6 to 9 in the form of Tris-Cl, and an alcohol (i.e., ethanol; paragraph 0059). Neither Qiagen nor Lineau et al explicitly teach a buffer having 0.2 to 2 M guanidine, 5 to 25% ethanol, and a buffered pH of 6 to 9.

However, Whitlow et al teach a buffer comprising 0.5 M guanidine, 20% ethanol, and the buffering agent Tris at pH 8.0, which as the added benefit of disrupting the interactions that maintain protein conformation (column 12, lines 1-17). Said disruption inactivates any remaining proteins present, thereby preventing any undesired reactions catalyzed by the proteins from occurring.

It would therefore have been obvious to a person of ordinary skill at the time the claimed invention was made to have further modified the method of Qiagen in view of Lineau et al with the wash buffer as taught by Whitlow et al with a reasonable expectation of success. The ordinary artisan would

Art Unit: 1634

have been motivated to make such a modification because said modification would have resulted in a method of preparing an RNA sample having the added advantage of preventing any undesired reactions catalyzed by the proteins from occurring by disrupting the interactions that maintain protein conformation, thereby disrupting the activity of the proteins, as explicitly taught by Whitlow et al (column 12, lines 1-17).

9. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Qiagen (The Qiagenologist Application Protocols, 3rd edition, Qiagen Inc., Chatsworth, CA, pages 1-53 (1990)) in view of Lineau et al (U.S. Patent Application Publication No. US 2002/0072110 A1, issued 13 June 2002) as applied to claim 1 above, and further in view of Crossway et al (U.S. Patent No. 4,996,144, issued 26 February, 1991).

Regarding claim 11, the method of claim 1 is discussed above on pages 3-6.

While Qiagen teaches DNA digestion (pages 20-21 and 53), neither Qiagen nor Lineau et al teach digestion with DNase of an RNA containing solution.

However, Crossway et al teach a method of purification of nucleic acids (e.g., RNA; Abstract, lines 3-5) using digestion with DNase with the added benefit of allowing differential detection of RNA only (column 5, lines 60-63).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the method of preparing an RNA sample as taught by Qiagen in view of Lineau et al with the DNase treatment as taught by Crossway et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because the modification would have resulted a method of preparing an RNA sample having the added advantage of allowing differential detection of RNA only as explicitly taught by Crossway et al (column 5, lines 60-63).

Art Unit: 1634

10. Claims 19-21 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colpan et al (U.S. Patent No. 6,383,393 B1, issued 7 May 2002) in view of Lineau et al (U.S. Patent Application Publication No. US 2002/0072110 A1, issued 13 June 2002).

Regarding claim 19, Colpan et al teach the method of preparing a sample substantially free of genomic DNA; namely, a method for purification and separation of nucleic acid mixtures (Abstract, lines 1-2). In a single exemplary embodiment, Colpan et al teach forming a lysate from a biological sample (column 2, line 65) followed by contacting a pre-filtration column with said lysate (column 7, lines 30-36), wherein said pre-filtration column comprises a fiber material, and wherein said fiber material has at least one layer of glass (column 7, lines 30-36). Essentially all genomic DNA in said lysate is removed to produce a filtrate; namely, RNA is separated and purified (i.e., genomic DNA is removed) by the column; column 6, lines 7-8). An RNA-containing precipitate is then formed by adding an organic solvent to the said filtrate because the column is washed with a buffer containing isopropanol (Example 1, column 8, lines 4-10).

Colpan et al do not teach contacting the precipitate with a polymeric membrane.

However, Lineau et al teach a method of preparing a nucleic acid sample (paragraph 0031). In a single exemplary embodiment, Lineau et al teach forming a lysate from a biological sample (paragraph 0007), followed by forming a precipitate of the nucleic acid by adding the alcohol isopropanol, which is an organic solvent (paragraphs 0036 and 0055). The precipitated nucleic acid is then trapped on a polymeric membrane (paragraph 0039), followed by collecting the nucleic acid containing precipitate (paragraph 0039). Lineau et al further teach the membrane contacting step has the added advantage allowing incorporation into high throughput applications and without substantially affecting the yield of the isolated nucleic acid (paragraphs 0037 and 101), wherein the nucleic acid that is purified is RNA (paragraph 0031).

As noted above, Lineau et al teach the polymeric membrane is a nylon membrane having a pore size, and thus a particle retention, of 5 microns (paragraph 0023), which is up to 10 microns. Claim 24

Art Unit: 1634

limits the membrane to nylon membranes. Thus, the nylon membrane of Lineau et al acts as a passive physical barrier as required by the claims.

It would therefore have been obvious to a person of ordinary skill at the time the claimed invention was made to have modified the method of Colpan et al with the additional steps of RNA purification as taught by Lineau et al with a reasonable expectation of success. The modification would result in an RNA containing precipitate as taught by Colpan, which is then subjected to the method of Lineau et al that follows the addition of the organic solvent to form a precipitate as also taught by Lineau et al. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in a method of preparing an RNA sample having the added advantage of allowing superior separation of the nucleic acid from cell derived contaminants as well as allowing incorporation into high throughput applications and without substantially effecting the yield of the isolated RNA as explicitly taught by Lineau et al (paragraphs 0037 and 101).

Regarding claim 20, the method of claim 19 is discussed above. Colpan et al also teach fiber material having a particle retention ranging from about 0.1 microns to about 10 microns; namely, the glass has a pore size of 1 micron (column 6, lines 60-67).

Regarding claim 21, the method of claim 19 is discussed above. Colpan et al also teach fiber material having a thickness ranging from about 50 microns to about 2000 microns (column 6, lines 60-67).

Regarding claims 23-24, the method of claim 19 is discussed above. Lineau et al also teach the polymeric membrane is a nylon membrane (i.e., claim 24) having a pore size, and thus a particle retention, of 5 microns (paragraph 0023), which is from about 0.1 to about 10 microns (i.e., claim 23).

11. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colpan et al (U.S. Patent No. 6,383,393 B1, issued 7 May 2002) in view of Lineau et al (U.S. Patent Application Publication No. US 2002/0072110 A1, issued 13 June 2002) as applied to claims 19 and 21 above, and further in view of the Aldrich Catalog (Aldrich Chemical Company, Milwaukee, WI, page T281 (1998/1999)).

Art Unit: 1634

Regarding claim 22, the method of claims 19 and 21 is discussed above on pages 8-10.

Neither Colpan et al nor Lineau et al teach the specific weights of the fiber material.

However, Aldrich teaches glass fibers in 2 in diameter bundles that are 22 feet long, weighing 454 g (page T281, column 2, paragraph 1). A filter layer having a 2 in (5.08 cm) diameter has an area of 0.00203 m²; therefore, a filter layer having a 2 in diameter and a length (i.e., the thickness of the layer in a column) of 0.25 in has a specific weight of 212 g/m², thereby meeting the limitation of the claim. Further, it is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph). In the instant case, Applicant must provide proof that the specific weight ranging from about 75 g/m² to about 300 g/m² as claimed represents a new and non-obvious property beyond what is commonly known in the art.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1634

13. Claims 19-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 11 of copending Application No. 10/914,920 in view of Harrington et al (U.S. Patent No. 6,361,972 B1, issued 26 March 2002). Both sets of claim are drawn to lysates (i.e., homogenates), glass fibers, RNA solutions, eluting the RNA from a polymeric membrane, nylon membranes, particle retentions, thicknesses, and specific weights of the glass fibers, and adding organic solvents. The claims of the '920 Application do not explicitly teach removing essentially all of the genomic DNA.

However, Harrington et al teach a method comprising purifying (i.e., isolating) RNA (column 9, lines 44-55) comprising removing all of the genomic DNA, which has the added advantage of removing molecules that complicate identification and analysis of novel genes (column 68, lines 20-27).

It would therefore have been obvious to a person of ordinary skill in the art to have modified the claims of the '920 application to remove essentially all of the genomic DNA to obtain the instantly claimed invention. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in the method of the '920 claims having the added advantage of removing molecules that complicate identification and analysis of novel genes as explicitly taught by Harrington et al (column 68, lines 20-27).

This is a provisional obviousness-type double patenting rejection.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

Art Unit: 1634

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER

Robert T. Crow
Examiner
Art Unit 1634

